UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION
PREVENTION

MEMORANDUM

DATE: June 21, 2013

SUBJECT: Efficacy Review for Per-Ox,
EPA Registration No. 833-4;
DP Barcode: D410288

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APPLICANT: Alex C. Fergusson, Inc.
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FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
Peroxyacetic acid	5.25%
Hydrogen Peroxide	22.00%
Inert Ingredient(s)	72.75%
Total	100.00%

I BACKGROUND

The product, Per-Ox (EPA Registration No. 833-4), is a registered food contact sanitizer for use in institutional, industrial and food processing facilities. The applicant has requested to amend the product to add claims for effectiveness against *Listeria monocytogenes* and *Salmonella typhimurium* as a sanitizing rinse for use on hard, non-porous surfaces in food processing, industrial, and institutional environments. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative (dated February 18, 2013), two studies (MRID 49058901 and 49058902), Form 8570-35 (Data Matrices), Statements of No Data Confidentiality Claims for both studies, and the proposed label.

II USE DIRECTIONS

The product is designed for sanitizing pre-cleaned, hard, non-porous, food contact surfaces such as pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in dairies, wineries, breweries, beverage plants, meat and poultry processing plants, seafood packaging plants, egg processing facilities, and eating establishments No organic soil load was used during testing, and the applicant does not make a one-step claim. The product is also designed for use on utensils, cups, dishes, plates, glasses, conveyor belts, peelers, slicers, and meat saws.

The product label indicates that the product may be used on hard, non-porous surfaces including metal, plastic and glass. Directions on the proposed label provided the following information regarding preparation and use of the product as a sanitizer for hard, non-porous surfaces: "Remove gross particulate matter with a warm water flush; wash equipment with detergent or cleaning solution; rinse equipment with potable water; prepare product solution by adding 1.0 to 1.7 fluid ounces to 5 gallons potable water. This provides 90 to 153 ppm peroxyacetic acid and 378 to 644 ppm hydrogen peroxide. Fill closed systems with diluted sanitizer solution and allow a contact time of one (1) minute, if sanitizing at temperatures of 5°C (40°F) or lower, use 1.6 fluid ounces of product to 5 gallons of potable water. If sanitizing against Listeria monocytogenes, use 1.25 to 1.7 fluid ounces of this product to 5 gallons of potable water. This will provide 112 to 153 ppm of peroxyacetic acid and 454 to 644 ppm of hydrogen peroxide. For open or not completely closed systems, use a coarse spray, mop/wipe or flood technique to apply the solution to the surface and allow a contact time of one (1) minute. Allow surfaces to drain thoroughly before resuming operation."

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces)

Sanitizing rinses may be formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, or anionic detergent-acid formulations. The effectiveness of such sanitizing rinses for previously cleaned, food contact surfaces must be substantiated by data derived from the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method. Data from the test on 1 sample from each of 3 different product lots, one of which is at least 60

days old against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) are required. When the effectiveness of the product in hard water is made, all required data must be developed at the hard water tolerance claimed. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, counts on the number controls for the product should fall between 75 and 125 x 10^6/mL for percent reductions to be considered valid. Label directions for use must state that a contact time of at least 1 minute is required for sanitization. A potable water rinse is not required (to remove the use solution for the treated surface) for products cleared for use on food contact surfaces under the Federal Food, Drug, and Cosmetic Act. Label directions must recommend a potable water rinse (to remove the use solution from the treated surface) under any other circumstances. These Agency standards are presented in DIS/TSS-4 and -17, as well as the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method.

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces; Additional Bacteria)

There are cases where an applicant requests to make claims of effectiveness against additional bacteria for a product that is already registered as a sanitizing rinse for previously cleaned, food contact surfaces. DIS/TSS-5 standards are silent on this matter. Confirmatory test standards would apply. For sanitizing rinses for previously cleaned, food contact surfaces, 2 product samples, representing 2 different product lots, must be tested against each additional microorganism. Results must show a bacterial reduction of at least 99.999% in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 49058901 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Listeria monocytogenes* (ATCC 19117)," for Per-Ox, by Becky Lien. Study conducted at ATS Labs. Study completion date – December 31, 2012. Project Number A14426.

This study was conducted against *Listeria monocytogenes* (ATCC 19117). Two lots (Lot Nos. 4001 and 4002) of the product, Per-Ox, were tested. ATS Protocol No. AFC01111412.GDST.1 was used for the test. Use solutions were prepared according to AOAC Methods. No hard water or soil was used in the testing. Suspensions were removed from bottles, filtered through sterile gauze pre-wetted with 1.00 mL of sterile PBDW and collected into a sterile tube. A 3.0 mL aliquot of PBDW was used to harvest each of 8 bottles. The culture suspension was adjusted to target approximately 1 x 10^{10} CFU/mL. Duplicate Erlenmeyer flasks containing 99.0 mL of the test substance at the concentration to be tested were prepared and placed into a waterbath at 24.0°C. The test substance was allowed to equilibrate for $\geq$ 20 minutes. Flasks containing the test substance were whirled in a circular motion stopping just before the suspension was added, creating enough residual motion of liquid to prevent pooling of the suspension at the point of contact with the test substance. A 1.00 mL aliquot of culture was added midway between the center of the edge of the surface with the tip of the pipette slightly immersed in the test solution. The flasks were further mixed following inoculation and exposed

for the duration of the 30 second exposure time at the exposure temperature. (24.0°C.) Following exposure, a 1.00 mL aliquot of the inoculated test substance was transferred to 9 mL of neutralizer, vortex-mixed and spread plated onto the subculture agar medium. All plates were incubated for 48+4 hours at 35-37oC. Following incubation, the subculture plates were visually examined for growth. Controls included those for purity, neutralizer sterility, diluent sterility, PBDW sterility, subculture agar sterility and neutralization confirmation.

2. MRID 49058902 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Salmonella enterica* serotype *typhimurium* (ATCC 23564)," for Per-Ox, by Becky Lien. Study conducted at ATS Labs. Study completion date – December 27, 2012. Project Number A14429.

This study was conducted against *Salmonella enterica* serotype – *typhimurium* (ATCC 23564). Two lots (Lot Nos. 4001 and 4002) of the product, Per-Ox, were tested. ATS Protocol No. AFC01111412.GDST.3 was used for the test. Use solutions were prepared according to AOAC Methods. No hard water or soil was used in the testing. Suspensions were removed from bottles, filtered through sterile gauze pre-wetted with 1.00 mL of sterile PBDW and collected into a sterile tube. A 1.50 mL aliquot of PBDW was used to harvest each of 8 bottles. The culture suspension was adjusted to target approximately 1 x 10^{10} CFU/mL. A spectrophotometric analysis was performed using a wavelength of 620 nm. The final absorbance value was 2.073. Duplicate Erlenmeyer flasks containing 99.0 mL of the test substance at the concentration to be tested were prepared and placed into a waterbath at 24.0°C. The test substance was allowed to equilibrate for ≥ 20 minutes. Flasks containing the test substance were whirled in a circular motion stopping just before the suspension was added, creating enough residual motion of liquid to prevent pooling of the suspension at the point of contact with the test substance. A 1.00 mL aliquot of culture was added midway between the center of the edge of the surface with the tip of the pipette slightly immersed in the test solution. The flasks were further mixed following inoculation and exposed for the duration of the 30 second exposure time at the exposure temperature. (24.0°C.) Following exposure, a 1.00 mL aliquot of the inoculated test substance was transferred to 9 mL of neutralizer, vortex-mixed and spread plated onto the subculture agar medium. All plates were incubated for 48+4 hours at 35-37oC. Following incubation, the subculture plates were visually examined for growth. Controls included those for purity, neutralizer sterility, diluent sterility, PBDW sterility, subculture agar sterility, and neutralization confirmation.

V RESULTS

MRID Number	Organism	Lot No.	Average No. Surviving (CFU/carrier)	Percent Reduction
49058901	*Listeria monocytogenes*	4001	8.0×10^{2}	99.999%
		4002	1.11×10^{3}	
49058902	*Salmonella enterica* – serotype typhimurium	4001	$< 1 \times 10^{1}$	99.999%
		4002	$< 1 \times 10^{1}$	

VI CONCLUSIONS

1. The submitted efficacy data (MRID 49058901 and 49058902) support the use of the product, Per-Ox, as a food contact sanitizer against *Listeria monocytogenes* and *Salmonella enterica* - serotype typhimurium on pre-cleaned, hard, non-porous surfaces for a contact time of 30 seconds using sterile, deionized water. A bacterial reduction of at least 99.999 percent over the parallel control was observed for both *Listeria monocytogenes* and *Salmonella enterica.* Neutralization confirmation testing met the acceptance criterion of growth within 1 $\log_{10}$ of the numbers control. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

VII RECOMMENDATIONS

1. The proposed label claims that the product, Per-Ox, is an effective sanitizing rinse on pre-cleaned, hard, non-porous, food contact surfaces against the following microorganisms for a 1-minute contact time:

Listeria monocytogenes, ATCC 19117
Salmonella enterica serotype – *typhimurium*, ATCC 23564

Data provided support these claims.

7. Making the following changes would improve the proposed label:

- On page 4 of the proposed label, it is recommended to list all organisms and ATCC numbers that the product is making claims for.

- On page 4 of the proposed label, the only surfaces listed are glass, metal and plastic. The applicant needs to provide more surface types (i.e., chrome, stainless steel, copper) that the product is recommended for.